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ATTORNEY DOCKET NO. CONFIRMATION NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE 1031 100391-02030 Martin T. Martin 10/039,471 10/19/2001 **EXAMINER** 35745 7590 02/17/2004 PATTERSON, CHARLES L JR KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT PAPER NUMBER ART UNIT 919 THIRD AVENUE 1652 NEW YORK, NY 10022

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/039,471	MARTIN, MARTIN T.
	Examiner	Art Unit
	Charles L. Patterson, Jr.	1652
Th MAILING DATE of this communication appears on the cover she t with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on		
2a) This action is <b>FINAL</b> . 2b) This	action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) ⊠ Claim(s) 1-45 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) □ Claim(s) is/are allowed.  6) □ Claim(s) is/are rejected.  7) □ Claim(s) is/are objected to.  8) ⊠ Claim(s) 1-45 are subject to restriction and/or election requirement.		
Application Papers		
9)☐ The specification is objected to by the Examiner.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary (	
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)     Paper No(s)/Mail Date	Paper No(s)/Mail Dai 5) Notice of Informal Pa 6) Other:	

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, 27-33, drawn to a method of modifying a biologically active target by introducing a chemical moiety to said target molecule, a composition capable of modifying the biologically active target, classified in class 435, subclass 41<sup>+</sup>.
- II. Claims 1-16, 27-33, drawn to a method of modifying a biologically active target by linking two or more target molecules, a composition capable of modifying the biologically active target, classified in class 435, subclass 41<sup>+</sup>.
- III. Claims 1-16, 27-33, drawn to a method of modifying a biologically active target by modulating an activity of said target molecule, a composition capable of modifying the biologically active target, classified in class 435, subclass 41<sup>+</sup>.
- IV. Claims 1-16, 27-33, drawn to a method of modifying a biologically active target by deactivating said target molecule, a composition capable of modifying the biologically active target, classified in class 435, subclass 41<sup>+</sup>.
- V. Claims 1-16, 27-33, drawn to a method of modifying a biologically active target by targeting said target molecule for degradation of clearance, a composition capable of modifying the biologically active target, classified in class 435, subclass 41<sup>+</sup>.
- VI. Claims 1-16, 27-33, drawn to a method of modifying a biologically active target by acylation, a composition capable of modifying the biologically active target, classified in class 435, subclass  $41^+$ .

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VII. Claims 1-16, 27-33, drawn to a method of modifying a biologically active target by glycosylation, a composition capable of modifying the biologically active target, classified in class 435, subclass  $41^+$ .

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- VIII. Claims 1-16, 27-33, drawn to a method of modifying a biologically active target by esterification, a composition capable of modifying the biologically active target, classified in class 435, subclass  $41^+$ .
- IX. Claims 1-16, 27-33, drawn to a method of modifying a biologically active target by transamidation, a composition capable of modifying the biologically active target, classified in class 435, subclass  $41^{+}$ .
- X. Claims 17-26, drawn to a catalytic antibody capable of chemically modifying a biologically active target molecule, wherein the target molecule is  $TNF\alpha$ , classified in class 435, subclass 188.5.
- XI. Claims 17-26, drawn to a catalytic antibody capable of chemically modifying a biologically active target molecule, wherein the target molecule is IL-4, classified in class 435, subclass 188.5.
- XII. Claims 17-26, drawn to a catalytic antibody capable of chemically modifying a biologically active target molecule, wherein the target molecule is IL-6, classified in class 435, subclass 188.5.
- XIII. Claims 17-26, drawn to a catalytic antibody capable of chemically modifying a biologically active target molecule, wherein the target molecule is VEGFr2, classified in class 435, subclass 188.5.
- XIV. Claims 34-35, drawn to a method of treating a disease condition associated with  $TNF\alpha$ , classified in class 424, subclass 94.1.

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XV. Claims 36-37, drawn to a method of treating a disease condition associated with VEGF, classified in class 424, subclass 94.1.

- XVI. Claims 38-39, drawn to a method of treating a disease condition associated with IL-4, classified in class 424, subclass 94.1.
- XVII. Claims 40-41, drawn to a method of treating a disease condition associated with IL-6, classified in class 424, subclass 94.1.
- XVIII. Claims 42-45, drawn to a method of modifying a biologically active target by contacting it with a catalyst that attaches a label, classified in class 435, subclass  $41^{+}$ .

The inventions are distinct, each from the other because:

Inventions (X-XIII) and (I-IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as by one of the processes in Groups I-IX, not related to modification of the target molecules in Groups X-XIII or one the treatment methods of Groups XIV-XVIII.

Inventions (X-XIII) and (XIV-XVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as to modify a target not associated with treating a treating a disease.

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The method of Group XVIII is different from all of the other methods in that it modifies the target molecule by attaching a label and none of the other methods do this.

It is noted that it is difficult to ascertain without a detailed reading of the specification whether any of the methods of Groups I-V involve the reactions of Groups VI-IX and whether Groups I-IX modify any of the target molecules included in Groups X-XIII. An explanation of this might lead to recombining some of the groups.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status informa-

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tion for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr

Primary Examiner Art Unit 1652

Patterson February 10, 2004